Draft Regulations

Draft Regulation

Financial Administration Act
(chapter A-6.001)

Fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product —Amendment

Notice is hereby given, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1), that the Regulation to amend the Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product, made by the Institut national d'excellence en santé et en services sociaux and appearing below, may be submitted to the Government for approval on the expiry of 45 days following this publication.

The draft Regulation makes amendments to the listing process under the Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product (chapter A-6.001, r. 6.1) to adjust the fees payable for some existing evaluations and to add other evaluations, with the corresponding fees, in order to take into consideration the total production costs of each evaluated item to reflect the level of resource use involved.

The draft Regulation will have an impact on manufacturers, who will have to pay the fees prescribed for scientific evaluation to the Institut national d'excellence en santé et en services sociaux.

Further information on the draft Regulation may be obtained from Françoise Thomas, Secrétaire générale et directrice des communications et du transfert de connaissances par interim, Institut national d'excellence en santé et en services sociaux, 2021, avenue Union, 12e étage, Montréal (Québec); telephone: 514 8732563, extension 29869; email: francoise.thomas@inesss.qc.ca.

Any person wishing to comment on the draft Regulation is requested to submit written comments within the 45-day period to the Minister of Health and Social Services, 1075, chemin Sainte-Foy, 15e étage, Québec (Québec) G1S 2M1.

CHRISTIAN DUBÉ,
Minister of Health and Social Services

ÉRIC GIRARD,
Minister of Finance

Regulation to amend the Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product

Financial Administration Act
(chapter A-6.001, s. 83.8)

1. The Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product (chapter A-6.001, r. 6.1) is amended by replacing the title by the following title:

"Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug, stable blood product or technology for listing purposes."

2. Section 1 is amended

(1) by replacing "or a stable blood product", in the first paragraph by ", stable blood product or technology";

(2) by adding "and determining its eligibility for scientific evaluation" at the end of the second paragraph.

3. Section 2 is replaced by the following:

"**2.** As used in this Regulation,

"scientific evaluation" means the structured evaluation of a drug, stable blood product or technology that can concern both its direct effects and its indirect and unintentional consequences, with the objective of guiding decision-making;

"manufacturer" means a person or group of persons that manufactures, produces, imports or sells a drug, stable blood product or technology, under its own name or under a brand name;

"nutritional formula" means a therapeutic nutritional product;

"indication" means an indication for use requested by a manufacturer;

"drug" means a product that can be entered on the list of medications referred to in section 60 of the Act respecting prescription drug insurance (chapter A-29.01), the list of medicines referred to in section 116 of the Act respecting health services and social services (chapter S-4.2), or the list of medications referred to in section 150 of the Act respecting health services and social services for Cree Native persons (chapter S-5), which is not otherwise contemplated by this Regulation;

"biosimilar drug" means a biologic drug introduced onto the Canadian market that is highly similar to a biologic drug already marketed in Canada and whose efficacy and safety do not diverge significantly from the reference biologic drug for the same indications;

"dressing" means a medical instrument used to treat wounds for an indication recognized on the lists of medications;

"radiopharmaceutical" means a radioactive product used to diagnose or treat a disease;

"stable blood product" means an acellular component of blood with the storage characteristics of drugs that is used to treat certain disorders due to an imbalance in the circulatory system or certain specific diseases and that can be entered on the Québec list of blood system products that may be distributed by Héma-Québec;

"cutting-edge therapeutic product" means a health product that is so new, complex and distinct that the current legislation is not able to take it into account, but that may still be entered on the list of medications referred to in section 60 of the Act respecting prescription drug insurance (chapter A-29.01), the list of medicines referred to in section 116 of the Act respecting health services and social services (chapter S-4.2), or the list of medications referred to in section 150 of the Act respecting health services and social services for Cree Native persons (chapter S-5);

"companion diagnostic" means a diagnostic test, a pharmacogenetic test or a therapeutic monitoring test designed to select only the patients for whom a treatment is likely to be beneficial among all the patients diagnosed with a given condition, based on their results for the predictive marker identified by the test;

"cellular or gene therapy" means a therapy to transfer living cells to a patient or to modify a patient's genetic materials in order to treat or heal a condition." .

4. Schedule I is replaced by the following:

"**SCHEDULE I**

(s. 1)

FEES PAYABLE FOR VARIOUS SCIENTIFIC EVALUATIONS

Scientific evaluation		**Fee**
Item evaluated	**Type of evaluation**	
New cellular or gene therapy	First evaluation	$89,796 per indication
	Reevaluation	$59,864 per indication
New drug with a companion diagnostic or new indication for a drug currently listed with a companion diagnostic	First evaluation	$68,844 per indication
	Reevaluation	$35,918 per indication
New drug or new indication for a currently listed drug or new stable blood product	First evaluation	$59,864 per indication
	Reevaluation	$35,918 per indication
New cutting-edge therapeutic product	First evaluation	$89,796 per indication
New radiopharmaceutical	First evaluation	$89,796 per indication
	Reevaluation	$35,918 per indication

Scientific evaluation		Fee
New medical device directly connected with the administration of a drug	First evaluation	$59,874 per submission
	Reevaluation	$35,918 per submission
New biosimilar drug	First evaluation	$8,980 per submission
	Subsequent evaluation (i.e., addition of an indication)	$8,980 per submission
	Reevaluation	$4,490 per submission
New strength, new content or new form of a currently listed drug	First evaluation	$8,980 per submission
	Reevaluation	$4,490 per submission
New nutritional formula or new combination of currently listed drugs or new diagnostic agent of a currently listed non-proprietary name	First evaluation	$5,986 per submission
	Reevaluation	$2,993 per submission
New dressing	First evaluation	$11,973 per submission
	Reevaluation	$5,986 per submission
Exemption from the application of the lowest price	Any exemption request	$8,980 per submission

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5. This Regulation applies to a request for a scientific evaluation received by the Institut national d'excellence en santé et en services sociaux on or after (*insert the date of coming into force of this Regulation*). It also applies to a request for a scientific evaluation received before (*insert the date of coming into force of this Regulation*) that is found to be incomplete in order to be eligible for a scientific evaluation and that requires the submission of supplementary information after that date.

6. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette officielle du Québec*.

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